President's Cancer Panel

Accelerating Progress in Cancer Prevention: The HPV Vaccine Example

Rationale

Globally, HPV infections cause most cervical cancers (about 500,000 new cases/year and 275,000 deaths), and a substantial proportion of cervical, vulvar, vaginal, anal, penile, oral cavity and oropharyngeal cancers as well as genital warts and recurrent respiratory papillomatosis. Substantial economic burden is associated with HPV-related conditions. The annual U.S. burden for cervical HPV-related disease ranges from $2.25 to $4.6 billion.

Vaccines protect against infection by the most common strains of oncogenic HPV (e.g., HPV 16, 18). Uptake of HPV vaccines in the United States, however, is sub-optimal. About 32% of age-eligible U.S. females and less than 2% of U.S. males have received the recommended three doses of vaccine. These rates are too low to achieve the population-wide potential of HPV vaccines to reduce cancer incidence and mortality. Increasing HPV vaccination rates in the United States and globally could effect a major reduction in HPV-related cancers.

Goals

- Develop a finite set of actionable recommendations that focus on effective and/or promising strategies to increase uptake of HPV vaccines in the United States among age-eligible males and females.
- Identify evidence about effective and/or promising strategies to increase vaccine use and lessons learned from HPV vaccine use in the United States and elsewhere.
- Identify topics and issues for which there are knowledge gaps that require further study.
- Identify practice and application issues that require attention.
- Identify issues related to global HPV vaccination strategy.

Approach

In three workshops, the President's Cancer Panel will assess the scientific basis for, current status of, and continuing efforts for effective vaccination against HPV-related cancers. The focus will include epidemiologic, behavioral, communication, policy, economic, global and other issues that influence effectiveness of HPV vaccines in reducing population cancer risks.

Participants' provocative questions submitted prior to workshops will help to inform discussions. Each workshop will include a series of short presentations and moderated discussions, with the goal of achieving consensus about key recommendations. Two participants will be invited to co-chair each workshop.

• Workshop 1: *HPV Vaccination as a Model for Cancer Prevention*	Jul. 24, 2012	San Francisco, CA
• Workshop 2: *Achieving Widespread HPV Vaccine Uptake*	Sept. 13, 2012	Washington, DC
• Workshop 3: *HPV Vaccination: Clinical Practices, Standards, and Economic Implications*	Nov. 16, 2012	Chicago, IL
• Workshop 4: *Challenges of Global HPV Vaccination*	Apr. 23-24 2013	Miami, FL

President's Cancer Panel

HPV Vaccination as a Model for Cancer Prevention

July 24, 2012 ▪ San Francisco, CA

Realization of a preventive vaccine for HPV serotypes most commonly associated with HPV-related cancers (cervical, vulvar, vaginal, anal, penile, oral cavity and oropharyngeal cancers as well as genital warts and recurrent respiratory papillomatosis) is a major advance in preventive oncology. This workshop will examine questions related to safety, efficacy, duration of protection, population impact, and next-generation vaccines. Broad areas include the following:

- **Fundamental science** that forms the foundation for development of HPV vaccines—specifically, basic, translational, and clinical research that brought vaccine from discovery to approval and practice
- **Surveillance and epidemiology** to assess global distribution of HPV-related cancers; durability of protection; whether booster is needed; number of doses required for immunity; virus latency; safety; cross-protection among multiple oncogenic HPV strains; and baseline incidence of HPV infection and cervical, vulvar, vaginal, anal, penile, oral cavity and oropharyngeal cancers among vaccinated populations will be examined.
- **Populations that are high priority for vaccination**—should recommended age targets be lowered? Should high-risk populations be specified?
- **Strategies for assessing population impact**, including modeling, designs appropriate for answering questions about population impact, and vaccination registries
- **Next-generation vaccines and improvements in HPV vaccine formulation and delivery** (e.g., circumventing need for vaccine refrigeration and lowering number of doses needed) have implications for future vaccines (e.g., those in development to cover multiple high-risk oncogenic HPV types and those targeting other cancer-related infectious agents). Other considerations include trade-offs regarding number of viruses covered vs. efficacy/safety and other factors. What issues are specific to developing next-generation HPV vaccines, such as combination vaccines? What are the barriers to progress?

Workshop Chairs

- **Doug Lowy, MD**, Chief, Laboratory of Cellular Oncology in the Center for Cancer Research, National Cancer Institute; Deputy Director, National Cancer Institute
- **Cosette Wheeler**, **PhD**, Professor of Pathology, University of New Mexico

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Achieving Widespread HPV Vaccine Uptake

September 13, 2012 ▪ Washington, DC

HPV vaccination rates in the United States should be increased if we are to achieve optimal population impact from vaccination. Workshop participants will examine a variety of perspectives as part of developing recommendations for increasing vaccine uptake. Perspectives and issues include but are not limited to the following:

- **Policies** that determine price, access and availability, and policies that influence where and by whom vaccines may be administered—and who is eligible to receive them, under what conditions and with what reimbursement—affect their use. Are mandates effective and, if so, under what conditions? What, if any, policy changes are needed to increase use of HPV vaccines?

- **Programmatic initiatives** central to vaccine dissemination include Vaccines for Children Program; AFIX; and initiatives led by state and local public health authorities.

- **Financing, development, and implementation** of a large-scale HPV vaccine efforts

- **Barriers** to greater use of HPV vaccines include the following:

  - ✓ **Programmatic:** there has been a shift of responsibility for immunization from public health departments to private providers who now vaccinate nearly 80% of U.S. children. What problems and benefits have resulted from this change in providers?
  - ✓ **Financial**: copayments for vaccine and physician visits; lack of incentives for parents to have their children vaccinated; burden on providers to keep vaccines stocked on site; and potential for free or low-cost vaccines all affect uptake. Do any of these factors inhibit uptake?
  - ✓ **Behavioral**: vaccine acceptability; among adolescents, perceived likelihood of infection with HPV; beliefs and perceptions about HPV vaccines (e.g., safety, impact on sexual behavior, true or not); perceived barriers to vaccination (e.g., parents' beliefs that vaccination will promote sexual activity among vaccinated children; the vaccine can be given later; cancer is not a major concern)
  - ✓ **Communication**: Physicians and other health providers are important sources of information (in their ability to initiate conversations with patients about concerns, clarify misunderstandings, and recommend vaccine). Can the Internet, social media, and tools like crowd-sourcing be used to inform and improve discussions and decisions about HPV vaccination?

- **Potential benefits and harms of bundling vaccines**—co-administering HPV vaccine with other vaccines for adolescents may increase acceptability and uptake (e.g., Tdap).

- **Lessons from countries** with high-vaccine coverage rates (e.g., Australia).

Workshop Chairs

- **Noel T. Brewer**, **PhD, MS,** Associate Professor, UNC Gillings School of Global Public Health; Director, Cervical Cancer-Free NC
- **Robert T. Croyle, PhD,** Director, Division of Cancer Control and Population Sciences, National Cancer Institute

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Clinical Practices, Standards, and Economic Implications

November 16, 2012 ▪ Chicago, IL

The impact of HPV vaccination on cervical, vulvar, vaginal, anal, penile, oral cavity and oropharyngeal cancer rates is not fully characterized. Continued use of available screening methods, even among vaccinated individuals, is needed to minimize cancer incidence and mortality. In this workshop, current clinical practice standards for cervical cancer screening—and related clinical and economic implications of widespread vaccination on other cancers and conditions—will be examined. The following are some of the issues and topics participants will examine.

- **As HPV vaccine uptake increases, potential changes in risk evaluation and clinical practice standards** should be anticipated to avoid redundant or outdated models of care.
- **Current screening guidelines** for cervical cancer (ACOG, ACS, USPSTF consensus guidelines released March 2012)
- **Management of cervical lesions** (consensus guidelines to be released September 2012)
- **Issues related to cost-effectiveness of widespread population vaccination for males and females:** for cervical cancer screening, estimations vary according to frequency and type of screening (e.g., yearly vs. every-three-year screening, pap vs. HPV DNA test).
- **Economic approaches** that could increase access to vaccines among vulnerable populations (e.g., tiered pricing, innovative financing mechanisms, interdisciplinary partnerships, insurance and public program reimbursement policies)
- **Potential economic effects** of increased vaccination rates on federal, state, and private health care and insurance costs, particularly in light of national changes in financing
- **Potential new providers** such as dentists
- **Additional tools and resources needed** to track changes in population risks as a result of widespread vaccination
- **Comparative effectiveness research initiatives**

Workshop Chairs

- **Marcus Plescia, MD, MPH,** MPH, Director, Division of Cancer Prevention and Control, Centers for Disease Control and Prevention
- **TBD**